DEC 2 9 2005

K053266

Premarket Notification 510(k) Summary
For MyoTrac Infiniti

Date Prepared: 20-10-2005

Applicant: Thought Technology Ltd
2180 Belgrave Avenue
Montreal Quebec
Canada H4A 2L8

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Design Coordinator
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Device Name

Trade Name:	MyoTrac Infiniti System
Common Name:	Powered muscle stimulator and biofeedback device
Classification Name:	89IPF, 84HCC ClassII (882.5050 and 890.5850)

Predicate Devices

Trade Name:	Danmeter AutoMove AM800 EMG Triggered Stimulator (K972997)
Classification Name:	89IPF, 84HCC, ClassII
Trade Name:	Mettler Electronics Corp Sys STIM 208 powered muscle stimulator (K031017)
Classification Name:	89IPF, ClassII

Description of Device:

The MyoTrac Infiniti device is an electrical muscle stimulator for contraction of muscles as indicated below.

The MyoTrac Infiniti is also an electromyography device. It is intended for medical purposes, such as to monitor and display the bioelectric signals produced by muscles, to stimulate peripheral nerves and to monitor and display the electrical activity produced by nerves. The indications for use are muscle re-education, relaxation and biofeedback.

Intended Use

Indications for use:

- Biofeedback, Relaxation and Muscle Reeducation.
- Relaxation of Muscle Spasms.
- Prevention or retardation of disuse atrophy.
- Increasing local blood circulation.
- Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis.
- Maintaining or increasing range of motion.
- Stroke Rehab by Muscle re-education.

Technical Characteristics Comparison to Predicate Device

MyoTrac Infiniti is compared to AutoMove AM800 (K972997) and Sys STIM 208 (K031017). The technical specifications of the MyoTrac Infiniti substantially fall within the range of the AutoMove AM800. The differences are that the MyoTrac Infiniti is able to deliver more charge per pulse and more power density than the AutoMove AM800 but still with in the range of Sys STIM 280 and power density limits specified by 21 CFR 890 5850 (Powered Muscle Stimulator) and outputs EMG RMS vs. EMG peak from the AutoMove AM800. These differences should not affect the safety or effectiveness of the device.

	PROPOSED DEVICE MyoTrac Infiniti	**Danmeter AutoMove AM800 EMG Triggered Stimulation K972997**	**SYS STIM 208 K031017**
Intended Use	Muscle Stimulation and EMG Biofeedback	Muscle Stimulation and EMG Biofeedback	Powered Muscle Stimulation
Primary Functions	Delivery of stimulation and reading of Electromyography	Delivery of stimulation and reading of Electromyography	Delivery of stimulation
Stimulator Output	0 – 100mA at 500ohms	0 -60mA at 2.5Kohms	0-184mA at 500 ohms
Waveform	Asymmetrical Balanced Pulsed Current	Biphasic, alternating and monophasic Current	Asymmetrical Biphasic Rectangle with zero net DC
Maximum Phase Charge	60µC	31µC	56µC
Frequency	2 – 100 Hz	10 - 100 Hz	1-80Hz
Peak pulse intensity	100mA	60mA	184mA
Pulse Width	50 - 400µS	100 – 400 µS	200-800µS
Ramps	0 – 10sec on and off ramp	0.5 sec to 10 sec	
Duty Cycle	On(sec): 2 - 20 Off(sec): 2 - 50	On(sec): 2 - 20 Off(sec): 2 - 50	ON 0.375 to 3.75sec OFF 0.375 to 3.75sec
Session Duration (min)	1 to 120 minutes	10 to 800 minutes or continue	
Programmable features	Frequency, Current intensity, pulse width, ramp up and down, session length, threshold trigger by the patient and the physician.	Frequency, Current, Pulse width, ramp up and down, session duration, threshold for trigger and duty cycle. By patient or physician.	
Surface Electrodes	K874469A AxelGaard electrodes for EMG or Stim.	PALS FLEX electrodes - AxelGaard - K8764469A	
	K935213 Electrodes Uni–Gel for EMG only		
	K903497A Triode Electrodes for EMG only		
	K903497A Single Electrodes for EMG only		
Current Density (full output)	Axelgaard Model 895220 0.24mA/cm² Axelgaard Model 895340 0.08mA/cm²	0.5 mA/ cm²	0.132mA/ cm²
Power Density (full output @ 500ohms)	Axelgaard Model 895220 16mW/cm²	13mW/cm²	12mW/ cm²

	Axelgaard Model 895340 5.3mW/cm^2		
EMG Ranges in µV	0-5, 0-10, 5-10, 0-20, 5-20, 10-20, 0-50, 10-50, 0-100, 50-100, 0-200, 50-200, 100-200, 0-500, 100-500, 0-1000, 0-2000	2 - 2000µV	N/A
EMG Bandwidth	20 – 500 Hz	50 – 1000 Hz	N/A
EMG Signal Processing	Root Mean Square (RMS)	Peak	N/A
EMG Detection	Bipolar	Bipolar	N/A
Work Period (sec)	2 – 20 seconds	2 – 20 seconds	0.375 to 3.75sec
Rest Period (sec)	2 – 50 seconds	2 – 50 seconds	0.375 to 3.75sec
Session Duration (min)	1-120 minutes	1 – 30 minutes	0-60minutes
Feedback Modes	Line Graph, Bar Graphs, Digital Display,	Bar Graphs, Digital Displays	Digital

Performance Data

Non-clinical tests were performed consisted of verification of the product specification, system validation, safety and EMC testing. Device equivalency is determined by a direct comparison of the device functional and hardware specifications of MyoTrac Infiniti system with the legally marketed predicate devices, Automove AM800 EMG triggered stimulator and Sys STIM 208 powered muscle stimulator. Such a comparison table is present in the above section

Biocompatibility:

The Axelgaard EMG/Stimulation electrodes (K874469A), Thought Technology single, triode and Uni-gel Electrodes for EMG (K903497A & K935213) have been laboratory tested for the safety of the materials and were found to be safe under the standard required for each test.

Conclusion:

The MyoTrac Infiniti system is safe and effective for its intended use. The MyoTrac Infiniti system is substantially equivalent to the predicate devices.

End of 510(k) Summary

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 29 2005

Thought Technology Limited
c/o Mr. Robert Mosenkis
CITECH
5200 Butler Pike
Plymouth Meeting, PA 19462

Re: K053266/S1
Trade/Device Name: MyoTrac Infiniti System
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: II
Product Code: IPF, HCC
Dated: December 14, 2005
Received: December 16, 2005

Dear Mr. Mosenkis:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: MyoTrac Infiniti System

Indications for Use:

The MyoTrac Infiniti system is indicated for the ongoing treatment of the following conditions: Relaxation of Muscle Spasms, Prevention or retardation of disuse atrophy, increasing local blood circulation, immediate post-surgical stimulation of calf muscles to prevent venous thrombosis, Maintaining or increasing range of motion and Stroke Rehab by Muscle re-education. It is also used for Biofeedback, Relaxation & Muscle Re-Education purposes.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhern

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K053266